<u>**REMARKS**</u>

The Non-Final Office Action dated August 5, 2008, has been received and reviewed. Prior to this amendment, each of claims 1-34 was rejected. Claims 1, 9-10, 12, 20-21, 23-26, 28-29, and 32-33 have been amended herein and claim 27 has been cancelled, as hereinabove set forth. Applicants respectfully request reconsideration of the present Application in view of the above amendments and the following remarks. Care has been exercised to introduce no new matter. Claims 1-26 and 28-34 are pending and are in condition for allowance.

<u>**Rejections based on 35 U.S.C. § 101**</u>

Claims 12-28 stand rejected under 35 U.S.C. § 101 on the basis that the claimed invention is directed to non-statutory subject matter. *See Office Action dated August 5, 2008*, pg. 2. Claim 27 has been cancelled herein and, as such, the rejection of claim 27 is rendered moot. The Office Action indicates that the method steps of independent claims 12 and 23 are not "tied to another statutory class and can be performed without the use of a particular apparatus." *See id.* at pg. 3. As amended herein, each of independent claims 12 and 23 recites "a computer-implemented method." As such, Applicants respectfully submit that independent claims 12 and 23, as amended herein, are directed to statutory subject matter.

For at least the above-cited reasons, it is respectfully requested that the 35 U.S.C. § 101 rejection of claims 12 and 23 be withdrawn. Each of claims 13-22, 24-26, and 28 depends, directly or indirectly, from one of independent claims 12 or 23, each reciting *a computer-implemented method*. As such, each of dependent claims 13-22, 24-26, and 28 incorporates the subject matter of amended independent claims 12 or 23. *See,* 37 C.F.R. 1.75(c). Accordingly, it is respectfully requested that the 35 U.S.C. § 101 rejection of dependent claims 13-22, 24-26, and 28 be withdrawn at least by virtue of their dependency.

Rejections based on 35 U.S.C. § 112

Claims 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for "failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." *Office Action dated August 5, 2008*, pg. 3. Claim 27 has been cancelled herein and, as such, the rejection of claim 27 is rendered moot. The Office Action indicates that independent claim 23 is "indefinite because it is unclear if the claim is directed to a product or a method." *See id.* As amended herein, independent claims 23 recites "[a] computer-implemented method for generating an analytic report." As such, Applicants respectfully submit that independent claim 23, as amended herein, is definite because it is clear that the claim is directed to a method.

For at least the above-cited reasons, it is respectfully requested that the 35 U.S.C. § 112 rejection of claim 23 be withdrawn. Each of claims 24-26, and 28 depends, directly or indirectly, from independent claim 23 reciting *a computer-implemented method.* As such, each of dependent claims 24-26 and 28 incorporates the subject matter of amended independent claim 23. *See,* 37 C.F.R. 1.75(c). Accordingly, it is respectfully requested that the 35 U.S.C. § 112 rejection of dependent claims 24-26 and 28 be withdrawn at least by virtue of their dependency.

Rejections based on 35 U.S.C. § 102(e)

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdeggal Brothers v. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 19133, 1920 (Fed. Cir. 1989); *see also,* MEP § 2131.

Claims 1-7, 9, 11-18, 20, 22-27, 29-32 and 34 have been rejected under 35 U.S.C. 102(e) as being anticipated by Rosenfeld et al., U.S. Patent No. 6,804,656 (hereinafter "Rosenfeld"). Claim 27 has been cancelled herein and, as such, the rejection of claim 27 is rendered moot. As Rosenfeld does not describe, either expressly or inherently, each and every element of the rejected claims, Applicants respectfully traverse the rejection as hereinafter set forth.

Initially, with reference to independent claims 1, 12, and 29, such claims are directed to systems and a method for analyzing clinically related data. Each of claims 1, 23, and 29, as amended herein, include clinically related data; a knowledge base; and *selectively performing comparative analysis of the clinically related data against the knowledge base, wherein the comparative analysis models or projects at least one facility-wide outcome based on an analysis of the clinically related data and a clinical guideline selected from the knowledge base.*

By way of contrast, Rosenfeld describes a system to monitor patients from a central command center. *See Rosenfeld,* col. 4, lines 53 – col. 5, line 2. Critical care units in various physical locations are linked to a command center that performs patient monitoring. *See id.* In Rosenfeld, "signals from the clinical data and video data are submitted to a relational database, which comprises 1) standardized guidelines for the care of the critically ill, 2) various algorithms to support the intensive care regimen, 3) order writing software so that knowledge-based recommendations and prescriptions for medication can be made based upon the clinical data, and 4) knowledge-based vital-sign/hemodynamic algorithms that key the intensivist to engage in early intervention to minimize adverse events." *Id.* at col. 5 lines 14-22. The relational database stores decision support analysis and "prompt[s] intensivists to provide care to

patients based upon . . . the decision support algorithms." *Id.* at col. 7, lines 5-40; *see also id.* at col. 8, lines 31-39.

While Rosenfeld refers to a relational database that assists in providing care to a patient, it is respectfully submitted that Rosenfeld does not discuss performing a comparative analysis that *projects at least one facility-wide outcome based on an analysis of the clinically related data and a clinical guideline selected from the knowledge base*. Rather, in Rosenfeld, guidelines are used to assist with providing care to a *specific patient*. Using guidelines to provide care to a specific patient, as in Rosenfeld, is in stark contrast to *projecting a facility-wide outcome* based on clinically related data and a particular clinical guideline selected from a knowledge base, as recited in independent claims 1, 12, and 29, as amended herein.

Turning now to independent claim 23, independent claim 23 recites a computer-implemented method for generating an analytic report. The method includes, as amended herein, receiving a first selection of one of a plurality of policies and procedures stored within a knowledge base; accessing clinically related data corresponding with a plurality of patients; selectively performing a comparative analysis of the clinically related data against the first selected policy or procedure contained within the knowledge base to provide an indication as to whether the first selected policy or procedure has been attained; receiving a second selection of one of the plurality of policies and procedures stored within a knowledge base; using the second selected policy or procedure and the clinically related data corresponding with a plurality of patients to perform a predictive analysis that projects at least one operational, financial, or facility-wide outcome that might result if the second selected policy or procedure is used by a clinical facility.

By way of contrast, Rosenfeld describes a system to monitor patients from a central command center. *See Rosenfeld,* col. 4, lines 53 – col. 5, line 2. Critical care units in various physical locations are linked to a command center that performs patient monitoring. *See id.* In Rosenfeld, "signals from the clinical data and video data are submitted to a relational database, which comprises 1) standardized guidelines for the care of the critically ill, 2) various algorithms to support the intensive care regimen, 3) order writing software so that knowledge-based recommendations and prescriptions for medication can be made based upon the clinical data, and 4) knowledge-based vital-sign/hemodynamic algorithms that key the intensivist to engage in early intervention to minimize adverse events." *Id.* at col. 5 lines 14-22. The relational database stores decision support analysis and "prompt[s] intensivists to provide care to patients based upon . . . the decision support algorithms." *Id.* at col. 7, lines 5-40; *see also id.* at col. 8, lines 31-39.

While Rosenfeld refers to a relational database that assists in providing care to a patient, it is respectfully submitted that Rosenfeld does not discuss using a *newly selected policy* or procedure and *clinically related data* corresponding with a *plurality of patients* to perform a predictive analysis that *projects at least one operational, financial, or facility-wide outcome that might result if the newly selected policy or procedure is used by a medical facility.* Rather, in Rosenfeld, guidelines are used to assist with providing care to a *specific patient.* Using guidelines to provide care to a specific patient, as in Rosenfeld, is in stark contrast to *projecting operational, financial, or facility-wide* outcomes resulting in instances when a *newly selected policy* not being used by a facility is implemented, as recited in independent claim 23, as amended herein. Further, the predictive analysis of claim 23 utilizes both a newly selected policy and clinically related data corresponding with a plurality of patients to project outcomes.

In Rosenfeld, however, any clinical data used is based on clinical data of the *specific patient* being monitored. *See Rosenfeld,* col. 5, lines 10-15; col. 43, lines 11-21. Accordingly, Rosenfeld does not describe using a newly selected policy and clinically related data associated with multiple patients to project outcomes.

In addition, it is respectfully submitted that Rosenfeld does not discuss performing a comparative analysis of clinically related data corresponding with a plurality of patients against a selected policy or procedure contained within a knowledge base to provide an indication as to whether the selected policy or procedure has been attained or achieved, as recited in independent claim 23. Rather, in Rosenfeld, guidelines are used to assist with providing care to a *specific patient.* Using guidelines to provide care to a specific patient, as in Rosenfeld, is in stark contrast to *providing an indication as to whether a selected policy has been attained by a medical facility,* as recited in independent claim 23, as amended herein. Further, the comparative analysis of claim 23 utilizes both a selected policy and *clinically related data* corresponding with a *plurality of patients* to provide an indication of a medical facility's achievement of the selected policy. In Rosenfeld, however, any clinical data used is based on clinical data of the specific patient being monitored. *See Rosenfeld,* col. 5, lines 10-15; col. 43, lines 11-21. Accordingly, Rosenfeld does not describe using a selected policy and clinically related data associated with multiple patients to provide an indication of a medical facility's policy achievement.

As Rosenfeld fails to describe, either expressly or inherently, each and every element as set forth in independent claims 1, 12, 23, and 29, it is respectfully submitted that Rosenfeld fails to anticipate claims 1, 12, and 29. Each of claims 2-7, 9, 11, 13-18, 20, 22, 24-26, 28, 30-32, and 34 depend, either directly or indirectly, from independent claims 1, 12, 23, and 29. As such, it is respectfully submitted that Rosenfeld fails to describe, either expressly or

inherently, each and every element of these claims for at least the above-cited reasons. Accordingly, withdrawal of the 35 U.S.C. § 102(e) rejection of claims 1-7, 9, 11-18, 20, 22-26, 28-32, and 34 is respectfully requested.

Rejections based on 35 U.S.C. § 103(a)

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. Graham v. John Deere Co., 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in Graham and to provide some reason, or suggestion or motivation found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention. See, Application of Bergel, 292 F. 2d 955, 956-957 (1961). Thus, in order "[t]o establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." See MPEP § 2143. Recently, the Supreme Court

elaborated, at pages 13-14 of KSR, it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application]." KSR v. Teleflex, 127 S. Ct. 1727 (2007).

Claims 8, 10, 19, 21, 28 and 33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld. With respect to claims 8 and 19, the Office Action indicates that "[a] predictable result of Rosenfeld would therefore be to include historical outcomes information in best practices for reuse when appropriate . . . ." *See Office Action dated August 5, 2008*, pg. 6. Applicants respectfully submit, however, that a knowledge base having historical outcomes information that is compared with clinical data is not a predictable result. With respect to claims 10, 21, 28, and 33, the Office Action indicates that "[a] predictable result of Rosenfeld would be to include whatever information necessary (e.g., patient mortality and morbidity information, clinical cost information etc.) to better treat a patient." *See id.* Applicants respectfully submit, however, that a facility-wide outcome that comprises estimated patient morality information, estimated patient morbidity information, or estimated clinical cost information is not a predictable result as indicated in the Office Action. Instead, the estimated patient morality information, estimated patient morbidity information or estimated clinical cost information are a facility-wide outcome projected based on clinically related data and a knowledge base.

Further, as Rosenfeld fails to teach or suggest all of the claimed features of amended independent claims 1, 12, 23, and 29, from which claims 8, 10, 19, 21, 28, and 33

depend, Applicants traverse this rejection. As discussed above, Rosenfeld fails to teach or suggest all of the claimed features of the rejected independent claims 1, 12, 23, and 29. For example, as discussed above, Rosenfeld fails to teach or suggest performing a comparative analysis that *projects at least one facility-wide outcome based on an analysis of the clinically related data and a clinical guideline selected from the knowledge base,* as recited in independent claims 1, 12, 23, and 29, as amended herein. Further, one skilled in the art would recognize that it would not be obvious to develop the comparative and predictive analyses as claimed in the present application to provide facility-wide outcome results from the system of patient treatment augmentation taught by Rosenfeld.

Thus, Applicants respectfully submit that Rosenfeld fails to teach or suggest each of the limitations of dependent claims 8, 10, 19, 21, and 33 for at least the above-cited reasons. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection. Each of claims 8, 10, 19, 21, and 33 is believed to be in condition for allowance and such favorable action is requested.

CONCLUSION

For at least the reasons stated above, claims 1-26 and 28-34 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or kfeimster@shb.com (such communication via email is herein expressly granted) – to resolve the same. It is believed that no fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112 with reference to attorney docket number CRNI.111056.

Respectfully submitted,

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